K111370

510(k) Summary
for the ODALYS™ Pedicle Screw System

SEP 2 1 2011

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the ODALYS™ Pedicle Screw System

Date Prepared: May 11, 2011

1. **Submitter:**
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Contact Person:
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1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** ODALYS™ Pedicle Screw System
Common Name: orthosis, pedicle screw system
Classification Name: orthosis, spondylolisthesis spinal fixation
orthosis, spinal pedicle fixation
21 CFR Sec. 888.3070
MNH
MNI
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
Moss Miami - K000536 (DePuy Spine)
PWB Lumbosacral Spine System – K920116 (Cross Medical Products, Inc.)

4. **Description of the device:**
The ODALYS™ Pedicle Screw System has been developed with the objective of providing the surgeon with an adaptable fixation system in order to carry out dorsal stabilization of the spine simply, quickly and effectively.

The system consists of a variety of color coded top loading pedicle screws. The pedicle screws are available in various lengths and diameters. The screw is connected to the rod via a rod connector. Two sizes of connectors are available, short and long. The long is used in cases of spondylolisthesis where the short connector would not be able to engage the rod. The rods are available in multiple lengths.

Materials:
The components are manufactured from titanium alloy (Ti 6Al 4V ELI) per ASTM F136.

Function:
The ODALYS™ Pedicle Screw System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments until fusion takes place.

5. **Substantial equivalence claimed to predicate devices:**
The ODALYS™ Pedicle Screw System is substantially equivalent to the Moss Miami and PWB Lumbosacral Spine System in terms of intended use, design, materials used, and performance.

6. **Intended Use:**

The ODALYS™ Pedicle Screw System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

As a pedicle screw system ODALYS™ Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

7. **Summary of Nonclincal Tests:**

The following tests were conducted:

- Static and dynamic compression per ASTM F1717
- Static torsion per ASTM F1717

The results of this testing indicate that the ODALYS™ Pedicle Screw System is equivalent to predicate devices.

8. **Clinical Test Summary:**

No clinical studies were performed

9. **Conclusions Nonclinical and Clinical:**

The ODALYS™ Pedicle Screw System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Kalitec Direct, LLC
% The OrthoMedix Group, Inc.
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

SEP 21 2011

Re: K111370
Trade/Device Name: ODALYS Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: July 30, 2011
Received: August 02, 2011

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111370

Device Name: ODALYS™ Pedicle Screw System

Indications for Use:

The ODALYS™ Pedicle Screw System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111370